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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/804,760	Confirmation No. 7688
Appellants	:	Meir S. Sacks et al.	
Filed	:	March 19, 2004	
Title	:	COMPOSITIONS FOR RAISING URIC ACID LEVELS AND METHODS OF USING THE SAME	
TC/A.U.	:	1614	
Examiner	:	Zohreh Vakili	
Docket No.	:	MSS 65055	
Customer No.	:	29694	

APPEAL BRIEF

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

March 1, 2010

Sir:

Appellants hereby appeal the rejection of the captioned case set forth in the Office Action dated March 31, 2009.

REAL PARTY IN INTEREST

The real party in interest is Meir S. Sacks, the assignee of the captioned application.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences that are believed to directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1 and 4-10 are pending in the application.

Claims 2 and 3 have been canceled.

Claims 1 and 4-10 stand rejected under 35 U.S.C. § 112(1) as allegedly failing to comply with the written description requirement.

Claims 1 and 4-10 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 4,472,387 to Laruelle et al. ("Laruelle et al. '387") in view of U.S. Patent No. 5,470,846 to Sandyk ("Sandyk '846") and further in view of U.S. Patent No. 6,264,994 to Castillo et al. ("Castillo et al. '994").

Claims 1 and 4-10 are appealed. A listing of the appealed claims is presented in the Claims Appendix.

STATUS OF AMENDMENTS

There are no outstanding amendments. As stated in the final Office Action dated March 31, 2009, the Amendment filed December 24, 2008 was entered into the present application.

SUMMARY OF CLAIMED SUBJECT MATTER

As recited in independent Claim 1, an embodiment of the invention provides a method of treating an Alzheimer's patient (paragraphs [00030] and [00031]), the method comprising administering a daily dosage consisting essentially of from 100 mg to less than 1,000 mg of hypoxanthine, xanthine and/or inosine to the patient (paragraphs [00032] and [00049]).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether Claims 1 and 4-10 are properly rejected under 35 U.S.C. § 112(1) as allegedly failing to comply with the written description requirement.

Whether Claims 1 and 4-10 are properly rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 4,472,387 to Laruelle et al. ("Laruelle et al. '387") in view of U.S. Patent No. 5,470,846 to Sandyk ("Sandyk '846") and further in view of U.S. Patent No. 6,264,994 to Castillo et al. ("Castillo et al. '994").

ARGUMENT

35 U.S.C. § 112

Claims 1 and 4-10 stand rejected under 35 U.S.C. § 112(1) as allegedly failing to comply with the written description requirement due to the recitation of the transitional phrase "consisting essentially of" in Claim 1. According to the Examiner, "the silence of the disclosure regarding *consisting essentially of* is not sufficient to now claim the exclusion of such steps because nowhere in the disclosure has Appellant discussed *consisting essentially of* in the context of the claimed method".

Appellants traverse this rejection. Claim 1 clearly recites that the daily dosage *consists essentially of* a specified amount of hypoxanthine, xanthine and/or inosine. The claimed method includes administering the claimed daily dosage composition to a patient. The phrase "consisting essentially of" does not modify any "step" recited in the claim, but rather modifies the "daily dosage" by restricting its composition to the recited amounts of hypoxanthine, xanthine and/or inosine, as well as any other additional ingredients that would not affect the basic and novel characteristics of the composition. The disclosure fully supports the claimed daily dosage composition and its administration to patients. Accordingly, the 35 U.S.C. § 112(1) rejection should be reversed.

35 U.S.C. § 103

Claims 1 and 4-10 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Laruelle et al. '387 in view of Sandyk '846 and further in view of Castillo et al. '994. According to the Examiner, Laruelle et al. '387 discloses a pharmaceutical composition suitable for increasing cerebral serotonin concentration comprising a serotonin precursor and inosine and hypoxanthine. In the final Office Action dated March 31, 2009, the Examiner states that treatment consists of administering to a mammal having a lower than normal cerebral serotonin level an amount of a pharmaceutical composition as presently claimed effective to increase the cerebral serotonin level, with daily dosages to 1 to 100 mg/kg being preferred. FROM PAGES 4-5

With respect to the "consisting essentially of" language in Claim 1, in the March 31, 2009 Office Action the Examiner states that such language has been treated as open-ended

"comprising" language, and that it is Appellants' burden to establish that a step practiced in a prior art method is excluded from the claims. However, as noted above, Appellants' "consisting essentially of" language modifies the composition of the daily dosage that is administered to an Alzheimer's patient, rather than any "step" of the recited method.

The Examiner relies upon Sandyk '846 as teaching a method of treating neurological and mental disorders which are associated with and/or related to pathogenetically deficient serotonin neurotransmission, with Alzheimer's disease being a disorder associated with deficient levels of serotonin.

The Examiner relies upon Castillo et al. '994 as teaching herbal compositions for intervention in Alzheimer's disease which may optionally include antioxidants.

In the Advisory Action dated October 15, 2009, the Examiner states that "Laruelle et al. is merely relied upon to show the dosage of the active agent".

It is respectfully submitted that the 35 U.S.C. § 103 rejection based upon Laruelle et al. '387, Sandyk '846 and Castillo et al. '994 is improper and should be reversed. Laruelle et al. '387 discloses pharmaceutical compositions based upon 5-hydroxytryptophan (5-HTP) and derivatives of 5-hydroxytryptophan, in combination with a nitrogenous heterocyclic compound selected from a group that includes inosine and hypoxanthine (see abstract and column 1, line 60 to column 2, line 16). According to Laruelle et al. '387, the combination of 5-HTP and derivatives of purine, pyrimidine or pyridine bases provide novel pharmaceutical compositions capable of correcting deficiencies of serotonin metabolism:

> The present invention provides novel pharmaceutical compositions capable of correcting the deficiencies of serotonin metabolism which are characterized in that they comprise an association of 5-HTP or a derivative thereof with derivatives of purine, pyrimidine, or pyridine bases, or with a combination of derivatives of these bases.
>
> The applicants have in fact observed that the combination of 5-HTP with a purine, pyridine, or pyrimidine heterocyclic base enables the cerebral levels of 5-HTP, serotonin and 5-hydroxyindolacetic acid (5-HIAA), which is the principal metabolite of serotonin, to be considerably increased. (column 3, lines 17-29; emphasis added)

The disclosed pharmaceutical compositions of Laruelle et al. '387 must have at least 5 percent 5-HTP that is chemically associated with the nitrogenous heterocyclic base (see column 3, lines 38-46). The 5-HTP-containing pharmaceutical compositions disclosed by Laruelle et al. '387 are said to triple blood levels of 5-HTP and 5-hydroxyindolacetic acid (5-HIAA), the principal metabolite of serotonin (column 4, lines 1-6). Laruelle et al. '387 discloses several specific examples of pharmaceutical compositions which were the subject of a pharmacological study. As set forth in columns 5-9, all of the studied compositions included significant amounts of 5-HTP. It is clear from the teachings of Laruelle et al. '387 that 5-HTP must be present in significant amounts in the disclosed pharmaceutical compositions, and represents a required active ingredient of the compositions that substantially affects serotonin levels when administered to patients.

In contrast, the dosage composition of the presently claimed method excludes the use of the levels of 5-HTP taught by Laruelle et al. '387 by reciting that the daily dosage administered to the Alzheimer's patent consists essentially of from 100 mg to less than 1,000 mg of hypoxanthine, xanthine and/or inosine to a patient. The "consisting essentially of" language excludes additional ingredients that would affect the basic and novel characteristics of the claimed daily dosage. Laruelle et al. '387 teaches that 5-HTP is a required active ingredient of the disclosed pharmaceutical compositions, and must be present in order to affect serotonin levels in patients. Laruelle et al. '387 therefore establishes that 5-HTP affects the basic and novel characteristics of the disclosed composition in that 5-HTP is the active ingredient that controls the serotonin levels in patients. It is clear to those skilled in the art that the elimination of the disclosed active ingredient from the composition of Laruelle et al. '387 would materially affect the basic and novel characteristics of the composition, i.e., the control of serotonin levels. The presently claimed administration of a daily dosage that excludes the levels of 5-HTP required by Laruelle et al. '387 patentably distinguishes over the reference.

Sandyk '846 and Castillo et al. '994 do not remedy the above-noted deficiencies of Laruelle et al. '387. Even if the secondary references could properly be combined with Laruelle et al. '387 as suggested by the Examiner, such a combination would not read on the presently claimed method of treating an Alzheimer's patient by administering a daily dosage consisting essentially of the recited amounts of hypoxanthine, xanthine and/or inosine to the patient.

Accordingly, Claim 1, and Claims 4-10 which depend therefrom, are patentable over Laruelle et al. '387 alone, or in combination with Sandyk '846 and Castillo et al. '994, and the 35 U.S.C. § 103 rejection based thereon should be reversed.

CONCLUSION

For the foregoing reasons, Appellants submit that the rejection of Claims 1 and 4-10 under 35 U.S.C. §§ 112(1) and 103(a) should be reversed. It is respectfully requested that the case is in condition for Notice of Allowance and, as such, that the case be remanded to the Examiner for the appropriate action.

Respectfully submitted,

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CLAIMS APPENDIX

1. A method of treating an Alzheimer's patient, the method comprising administering a daily dosage consisting essentially of from 100 mg to less than 1,000 mg of hypoxanthine, xanthine and/or inosine to the patient.

4. The method of Claim 1, wherein the daily dosage comprises an antioxidant.

5. The method of Claim 4, wherein said antioxidant is selected from vitamin C, vitamin C derivatives and vitamin E.

6. The method of Claim 4, wherein said antioxidant comprises a polyphenol.

7. The method of Claim 4, wherein said antioxidant comprises vitamin C and a polyphenol.

8. The method of Claim 1, wherein said daily dosage of hypoxanthine, xanthine and/or inosine comprises a maximum of 500 mg.

9. The method of Claim 1, wherein the daily dosage consists essentially of hypoxanthine.

10. The method of Claim 1, wherein the daily dosage consists essentially of inosine.

EVIDENCE APPENDIX

N/A

RELATED PROCEEDINGS APPENDIX

N/A